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IN THE

Supreme Court of the United States

OCTOBER TERM, 1956

V. E. IRONS, INC., AND V. E. IRONS, *Petitioners,*

v.

UNITED STATES OF AMERICA, *Respondent.*

PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FIRST CIRCUIT

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PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FIRST CIRCUIT

Petitioners pray that a writ of certiorari issue to review the judgment of the United States Court of Appeals for the First Circuit, entered in the above-entitled case on April 24, 1957.

CITATIONS TO OPINION BELOW

The District Court did not render an opinion. The opinion of the Court of Appeals, printed in Appendix A, *infra,* p. 1a, has not yet been published.

JURISDICTION

The judgment of the Court of Appeals was entered on April 24, 1957 (R. 1049). The jurisdiction of this Court is invoked under 28 U.S.C. 1254(1).

QUESTIONS PRESENTED

1. Whether the construction by the Court of Appeals of Section 502(f)(1) of the Federal Food, Drug, and Cosmetic Act, (21 U.S.C. 352 (f)(1)), under which the "labeling" of a drug product must contain directions for use for conditions specified in oral lectures and advertising, not constituting labeling under Section 201(m) of the Act (21 U.S.C. 321(m), renders Section 502 (f)(1) invalid as a matter of constitutional law because of the resultant vagueness and indefiniteness.

2. Whether this construction of Section 502(f)(1) by the Court of Appeals is correct.

3. Whether, where a criminal information charges a defendant with having "caused" the introduction or delivery for introduction into interstate commerce of a misbranded drug product, the Government must charge and prove wilfulness pursuant to 18 U.S.C. 2(b), as amended.

4. Whether material error was committed by the district court, constituting a miscarriage of justice, in refusing to permit expert opinion testimony on behalf of petitioners relating to the issue of whether the representations alleged to have been made by petitioners had in fact been made.

STATUTES INVOLVED

The statutory provisions involved are Sections 201 (m), 301(a), 502(a) and 502(f)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(m), 331(a), 352(a), 352(f)(1)), and 18 U.S.C. 2(b), as amended. They are printed in Appendix B, *infra*, p. 23a.

STATEMENT

Petitioners distribute in interstate commerce various natural vitamin products. In the marketing of their products, petitioners lay great stress upon the fact that they are selling only natural vitamins, as distinguished from high potency synthetic vitamins. There is a crusading school of thought in this country, although it appears to be a minority view, which is of the firm opinion that natural foods, including natural vitamins, are of far greater value in aiding good health than foods and vitamins produced synthetically. The Government prosecuted the petitioners by an information containing six counts. In each of Counts II to VI, the Government charged that the petitioners had falsely represented their products as a cure or treatment for various diseases in violation of Section 502(a) of the Act (21 U.S.C. 352 (a)), and that the labeling of petitioners' products had not borne adequate directions for use under Section 502(f)(1) (21 U.S.C. 352(f)(1)). The Government offered proof, which was admitted in evidence, that conditions had been adverted to in oral lectures and advertising, and that the labeling did not contain directions for use for these conditions. Count I charged that the label of petitioners' products had not contained information required by Section 403(j) of the Act (21 U.S.C. 343(j)), and the regulations issued thereunder. After

trial, the jury found the petitioners guilty on all counts.[1] The District Court sentenced petitioner V. E. Irons to serve one year in jail on each of the six counts of the information, to run concurrently, and sentenced petitioner V. E. Irons, Inc., to pay a fine of $1,000 on each count.

REASONS FOR GRANTING THE WRIT

Petitioners submit that the construction of Section 502(f)(1) of the Act by the Court of Appeals raises an important constitutional question as to whether the Section, as so construed, is rendered invalid for vagueness and indefiniteness. Petitioners further urge that the Court of Appeals has incorrectly decided an important question of Federal law, the construction of Section 502(f)(1), and that the constitutional question and question of statutory construction have not been, and should be, settled by this Court. There have been numerous criminal prosecutions under the Federal Food, Drug, and Cosmetic Act similar to that under which the petitioners were convicted, and many more condemnation actions bottomed on the same legal theory. Settlement of these questions, involving both liberty and property, is, therefore, in the public interest. A further important question, not yet decided by this Court, is whether 18 U.S.C. 2(b), as amended, is applicable to prosecutions alleging violations of the Federal Food, Drug, and Cosmetic Act and other laws where "causing" is charged in the information or indictment. This presents a question of substantial importance in the enforcement of criminal law.

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[1] It is not known whether the verdict on Counts II to VI was based on the charge under Section 502(a), the charge under Section 502(f), or both.

There is a conflict in the lower courts as to whether expert opinion testimony is admissible on the issue of whether representations alleged to have been made by a defendant had in fact been made. This is of particular significance since the courts have permitted the Government to introduce such testimony in prosecutions but have refused to permit defendants to introduce such testimony in defense.

1. These major issues, which had been raised below by petitioners, were not met by the Court of Appeals. Petitioners contended that if Section 502(f)(1) were so construed as to require that the labeling of a drug product must contain directions for use for conditions referred to in oral lectures or advertising, not constituting "labeling", the Section was rendered void for vagueness and indefiniteness. The only discussion of this point in the twenty page opinion of the Court of Appeals is the statement, infra, pp. 18a, 19a, that "it is a bit late in the day to sustain the assertion that the Federal Food, Drug, and Cosmetic Act is unconstitutionally vague." Petitioners also urged below that inasmuch as the Government had chosen to charge that petitioners had "caused" the Commission of the offenses complained of, the failure, in each of the six counts of the information, to charge and prove wilfulness, was fatally defective in view of the provisions of 18 U.S.C. 2(b), as amended. The Court of Appeals apparently adverted, *infra*, p. 18a, to this point by stating that "Appellants present a variety of other defenses, some of which are clearly untenable".

2. The construction of Section 502(f)(1) by the Court of Appeals renders the Section void for vagueness and indefiniteness. A statute which forbids the doing of an act in terms so vague that men of com-

mon intelligence must necessarily guess at its meaning, and differ as to its application, violates the first essential of due process of law. *Connally* v. *General Construction Co.*, 269 U.S. 385. Even if the Section were construed so as to require directions for use only for the conditions specified in the "labeling" of the product, the Section would still have distinct elements of ambiguity. What are "adequate directions for use?" How full must directions be to meet the test of adequacy? Adequate directions in what respects, in what conditions, and for whom? How can the ordinary person possibly know what "adequate directions for use" contemplate? But the Government's construction of the Section, requiring, in an Act devoted to "labeling", that labeling bear adequate directions for use for conditions mentioned in oral lectures delivered perhaps thousands of miles away from the shipment of the product or the location of the distributor, magnifies the ambiguity so as to render the Section impossible for the ordinary person to grasp by a reading of its language.

As this Court said in *Cardiff* v. *United States*, 344 U.S. 174, holding invalid for indefiniteness Section 704 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 374):

> The vice of vagueness in criminal statutes is the treachery they conceal either in determining what persons are included or what acts are prohibited. Words which are vague and fluid (Cf. United States v. L. Cohen Grocery Co., 225 U.S. 81, 65 L. ed. 516, 41 S. Ct. 298, 14 ALR 1045) may be as much of a trap for the innocent as the ancient laws of Caligula.

Applicability of the principle for which that case stands has been shadowed by some doubt cast by cases holding constitutionally valid certain statutes prohibiting or requiring, in language which seems somewhat vague, certain conduct. See, e.g., *United States* v. *Petrillo,* 332 U.S. 1. Petitioners submit that the rationale lies in whether the statute in question ties the prohibited act to a specific intent or purpose to achieve an indicated result. Apparently somewhat indefinite language may be upheld if the statute in question makes intent to achieve a proscribed purpose an element of the crime. See *Hygrade Provision Co.* v. *Sherman,* 266 U.S. 497; *Gorin* v. *United States,* 312 U.S. 19; *F. & A. Ice Cream Co.* v. *Ardens Farm Co.,* 98 F. Supp. 180 (S. D. Calif.). If this is correct, Section 502(f)(1) is clearly within the class of statutes that offend due process. For not only is wilfulness not an element of the crime under the Federal Food, Drug, and Cosmetic Act, but the penalties of the law may be imposed upon one wholly innocent of knowledge or intent to achieve a purpose proscribed by the statute. *United States* v. *Dotterweich,* 320 U.S. 277.

3. The construction of Section 502(f)(1) by the Court of Appeals which, we submit, accentuates the constitutional infirmity, was not only not required but was incorrect. It took five years. (1933-1938) to pass the Federal Food, Drug, and Cosmetic Act. It is clear, from a study of the legislative history, that every important and controversial problem and proposal, as well as a myriad of unimportant problems and proposals, was discussed and thrashed out in the greatest detail. Yet, not a word appears indicating that the Congress intended Section 502(f)(1) to apply to conditions referred to in oral statements or advertising not constituting labeling.

The Government refers to Senate Report No. 361, S. 5, 74th Cong., and Senate Report No. 493, S. 2800, 73d Cong., as disclosing the intent of Congress that labeling must contain directions for use for conditions adverted to in oral lectures and advertising. But the portions of these reports upon which the Government relies were not referring to the section of these bills providing that labeling must contain adequate directions for use, but to entirely different sections defining the various terms used in the bills. And these reports contain no reference whatever to the effect that the provisions with respect to directions for use apply to oral lectures and advertising as well as labeling. Further, these reports accompanied early bills which contained provisions vesting jurisdiction of advertising as well as labeling in the Food and Drug Administration. Thus, as was to be expected, the committees lumped the two together. But when Congress ultimately determined, in the amended Federal Trade Commission Act, to vest jurisdiction of advertising in the Federal Trade Commission, the bills which were then introduced and which culminated in the enactment of the Federal Food, Drug, and Cosmetic Act, and the applicable reports, contained not one reference to any design of Congress to give to the Food and Drug Administration, by indirection, the very jurisdiction over advertising which had already been vested in the Federal Trade Commission. The Federal Food, Drug, and Cosmetic Act, as finally enacted, defined "labeling" but not "advertisement". The amended Federal Trade Commission Act defined "false advertisement" but not labeling. (See 15 U.S.C. 41, 55 et seq.)

Congress knew the difference between the ordinary concepts of labeling and advertising. See Section

301(1) (21 U.S.C. 331(1)), prohibiting "the using, on the labeling of any drug or in any advertising relating to such drug, of any representation or suggestion" that a new-drug application has been approved by the Food and Drug Administration.

Another indication that Congress was and is quite aware of the distinction between advertising and labeling is found in the Oleomargarine Act, 64 Stat. 20. In that statute, Congress referred specifically to labels and sales, and amended the Federal Food, Drug, and Cosmetic Act in such connection, and further referred to advertisements and amended the Federal Trade Commission Act to cover the advertising of margarine.

Of particular interest is the factory inspection amendment to the Federal Food, Drug, and Cosmetic Act (67 Stat. 476, Sec. 704 of the Act, 21 U.S.C. 374, as amended). That amendment provides that "The using, in labeling, advertising or other sales promotion of any reference to any report or analysis furnished" in connection with a factory inspection shall be a criminal offense. Again, it will be seen that when Congress wished to direct its attention to advertising, as well as labeling, it made its intention entirely clear.

4. The failure to charge or prove wilfulness in the information was fatally defective. Each of the six counts charged the petitioners with "causing" a misbranded product to be introduced and delivered for introduction into interstate commerce. The criminal provisions of the Federal Food, Drug, and Cosmetic Act must be read together with Section 2 of Title 18, which qualifies all Federal criminal statutes. For example, under this Section one would be punished as a principal for aiding or abetting in the commission

of an act prohibited by another statute, including the Federal Food, Drug, and Cosmetic Act, even though that statute is silent as to aiders or abettors. Section 301(a) of the Federal Food, Drug, and Cosmetic Act, read together with 18 U.S.C. 2(b), makes the *causing* of the introduction and delivery for introduction into interstate commerce of a violative product a crime only if the causing was wilful. The first four sections of Title 18, including Section 2, are directed at any violation of Federal law, not merely those contained in Title 18. Many subsequent sections of that Title (see, for example, Sections 5, 6, 7, 9, 11, 12) refer to "this title", but the first four sections are not so limited. 18 U.S.C. 2(b) was enacted subsequent to the passage of the Federal Food, Drug, and Cosmetic Act in 1938, and in 1951 the requirement of wilfulness was added to 18 U.S.C. 2(b). In connection with criminal statutes, which must be strictly construed, it is submitted that it cannot be assumed that Congress chose to circumscribe 18 U.S.C. 2(b) by taking from within its coverage offenses under the Federal Food, Drug, and Cosmetic Act, even though the latter statute also directs itself to "causing."

This is particularly true since the construction which we urge does not limit in any way the substance of the latter statute. This Court held, in *United States* v. *Dotterweich*, 320 U.S. 277, that it is not necessary to allege or prove guilty knowledge or intent in prosecutions instituted under the Federal Food, Drug, and Cosmetic Act. The petitioners could have been charged, as were the defendants in the *Dotterweich* case, with having introduced or delivered for introduction into interstate commerce violative products. In

that event, the Government would not have had the burden of proving intent, let alone wilfulness. But here the Government chose to charge the petitioners with having "caused" the introduction and delivery for introduction into interstate commerce of the violative products and, therefore, took it upon itself to assume the burden, under 18 U.S.C. 2(b), of charging and proving wilfulness.[2]

5. Material error was committed in the refusal to permit expert opinion testimony on behalf of petitioners with respect to the issue of whether petitioners made the representations as charged in the information.

The information alleges that petitioners made various representations to the public to the effect that their product is effective in the cure and treatment of various specific diseases such as cancer, arthritis, heart trouble, diabetes, asthma, etc., and that the product was represented for special dietary uses. These charged representations constitute the foundation for the criminal acts set forth in all of the six counts.

The petitioners attempted to negate these allegations by the proffer of expert opinion testimony. The district court committed material error in refusing to permit such offers of proof. Reference is specifically made to the examination of Dr. N. Philip Norman (R.

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[2] The Court of Appeals also did not advert to the fact that one who causes is an aider and abettor, and that it is essential to the conviction of one so charged that there be proof that there was another person who did the prohibited act. This was not established at the trial. See *Morgan* v. *United States*, 159 F. 2d 85, 87 (C.A. 10); *Malatkofski* v. *United States*, 179 F. 2d 905, 916 (C.A. 1); *United States* v. *Horton*, 180 F. 2d 427, 430-431 (C.A. 7).

455-457).[3] In refusing such testimony, the Court stated that the question was a factual matter for the jury, and therefore, not proper. The district court was correct in stating that the ultimate issue was an issue of fact for the jury. However, that did not make the offer of proof objectionable. Although the jury must make the final determination of fact, proper evidence is admissible, and, in fact, invaluable, to enable the jury to reach its decision.

The necessity of such evidence in aid to the jury is magnified in this case, where we are dealing with charged representations created by taking words out of context from the petitioners' labeling material and by the creation of alleged representations in the form of English words other than the language of the label-

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[3] (R. 455, 456)

Q. And from your reading of the literature in the government's exhibit, do you have an opinion as to whether or not the defendants are claiming cures for specific diseases?

Mr. Lewald: I pray your Honor's judgment to that question.

The Court: Excluded.

Mr. Foley: May I argue the point?

The Court: No. It is for the jury.

(R. 457)

Mr. Foley: And that was, "Considering the literature as a whole, what is your opinion as to the fair import and meaning of the literature".

The Court: It is practically the same question.

Mr. Foley: Well, I think it reads a little differently. One is whether it takes—there are a lot of other things besides cures that have been alleged by the government.

The Court: It is a companion question.

Mr. Foley: Oh, yes, I agree to that.

The Court: And for the same reasons expressed, it is a factual matter for the jury, one of the allegations in the information that the government is to prove.

ing itself. The Government's allegations of alleged representations go beyond the express language of petitioners' labeling.

The type of evidence which petitioners attempted to introduce to defend themselves against the criminal charges is the same kind of evidence heretofore used by the Government, including the Food and Drug Administration, where such evidence served its purpose. *United States* v. *38 Dozen Bottles, More or Less, Labelled in Part Tryptacin,* 114 F. Supp. 461 (1953); *Charles of the Ritz Distributors Corporation* v. *Federal Trade Commission,* 143 F. 2d 676 (C.C.A. 2); *Federal Trade Commission* v. *National Health Aids, Inc. et al.,* 108 F. Supp. 340 (D. Md.); *Benton Announcements, Inc.* v. *Federal Trade Commission,* 130 F. 2d 254 (C.C.A. 2).

In the instant case, the Government did not introduce any evidence in support of its charged representations as it had done in the above-cited cases. When petitioners attempted to employ such evidence, by way of defense, the Government objected and the Court sustained said objection.

In *United States* v. *38 Dozen Bottles, More or Less, Labelled in Part Tryptacin,* 114 F. Supp. 461 (D. Minn.), the Government used the same kind of testimony to prove a similar charged representation of alleged "cure" and in *Stanley Laboratories, Inc.* v. *Federal Trade Commission,* 138 F. 2d 388 (C.A. 9), the Government used the testimony of physicians both as to their own opinion and their opinion of the effect of the advertisement upon the consumer to prove the meaning of advertising material. In both instances, the Court upheld the right of the Government to employ such expert opinion testimony.

The Court of Appeals in the instant case failed to answer this submission of error and further failed to discuss or distinguish the above-cited cases with respect to their applicability to the instant case. It is respectfully submitted that material and prejudicial error was committed by the refusal to permit petitioners to defend themselves against the charges set forth in the information.

Until this Court rules on this issue, we will be left with two different rules of law with respect to the same question. This conflict has created an injustice in that the division among the courts upholds such evidence when employed by the Government and denies it when employed by defendants.

CONCLUSION

For the foregoing reasons, this petition for a writ of certiorari should be granted.

Respectfully submitted,

VINCENT A. KLEINFELD
MILTON A. BASS
Counsel for Petitioners

May 24, 1957.

APPENDIX A

Opinion

UNITED STATES COURT OF APPEALS
FOR THE FIRST CIRCUIT

No. 5193

V. E. IRONS, INC., ET AL., *Defendants, Appellants,*

v.

UNITED STATES OF AMERICA, *Appellee.*

Consolidated Appeals From The United States District Court For The District of Massachusetts

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Before MAGRUDER, *Chief Judge,* and WOODBURY and HARTIGAN, *Circuit Judges.*

MILTON A. BAIS and VINCENT A. KLEINFELD for appellants.

GEORGE H. LEWALD, Assistant U. S. Attorney, with whom ANTHONY JULIAN, United States Attorney, JOSEPH L. MAGUIRE, Special Assistant U. S. Attorney, and WILLIAM W. GOODRICH, Assistant General Counsel, Department of Health, Education, and Welfare, were on brief, for appellee.

OPINION OF THE COURT

April 24, 1957

MAGRUDER, *Chief Judge.* V. E. Irons, Inc., and V. Earl Irons in his individual capacity stand convicted, after a three-weeks trial, on a six-count information for causing the introduction into interstate commerce of misbranded

food and drugs in violation of the Federal Food, Drug, and Cosmetic Act,[1] 52 Stat. 1040, as amended, 21 U.S.C. § 301 *et seq.*

Count I of the information charged that the defendants (appellants herein) caused to be introduced into interstate commerce articles of food, known as Vit-Ra-Tox 21A (raw veal bone, defatted wheat germ, and the concentrate of juices of young, green cereal shoots) and Vit-Ra-Tox 21B (garlic derivative, wheat germ, and lecithin as emulsifiers), which were misbranded under 21 U.S.C. § 343 (j)[2] in that they "purported to be and [were] represented as a food for special dietary uses by man by reason of [their] vitamin and mineral content and [their] label[s] failed to bear such information concerning [their] vitamin and mineral properties as had been determined to be and by regulations[3] pre-

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[1] Evidence introduced at the trial seems conclusively to establish that the defendants did introduce their products into interstate commerce. No issue as to this has been seriously pressed on appeal.

[2] § 343. Misbranded food.

A food shall be deemed to be misbranded— . . .

(j) If it purports to be or is represented for special dietary uses, unless its label bears such information concerning its vitamin, mineral, and other dietary properties as the Administrator determines to be, and by regulations prescribes as, necessary in order fully to inform purchasers as to its value for such uses.

[3] The pertinent regulations are as follows:

§ 125.2 *General label statements.* (a) If a food (including food to which anyone or more of §§ 125.3 to 125.8, inclusive, is applicable) purports to be or is represented for any special dietary use by man, its label shall bear a statement of the dietary properties upon which such use is based in whole or in part. Such statement shall show the presence or absence of any substance, any alteration of the quantity or character of any constituent, and any

scribed as necessary in order fully to inform purchasers as to [their] value for such uses".

Count II charged that the appellants caused to be introduced into interstate commerce articles of drug known as Vit-Ra-Tox 21A and Vit-Ra-Tox 21B (the same products referred to in Count I) which were (a) misbranded under

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other dietary property of such food upon which such use is so based.

(b) If a food (including food to which anyone or more of §§ 125.3 to 125.8, inclusive, is applicable) purports to be or is represented for special dietary use by reason of its use for treating any disease resulting from a dietary deficiency in man, its label shall bear, in addition to the information required under paragraph (a) of this section, adequate directions for such use.

§§ 125.3 *Label statements relating to vitamins.* (a) (1) If a food purports to be or is represented for special dietary use by man by reason of its vitamin property in respect of:

Vitamin A or its precursors,
Vitamin B_1 (thiamine),
Vitamin C (ascorbic acid),
Vitamin D, or
Riboflavin (vitamin B_2, vitamin G).

the label . . . shall bear a statement of the proportion of the minimum daily requirement for such vitamin supplied by such food when consumed in a specified quantity during a period of one day. . . .

(2) If a food purports to be or is represented for special dietary use by man by reason of its vitamin property in respect of any vitamin not listed in subparagraph (1) of this paragraph, the label shall bear a statement of the quantity of such vitamin in a specified quantity of such food. The quantity of food specified as required by this section, shall be the quantity customarily or usually consumed during a period of one day or a quantity reasonably suitable for and practicable of consumption within such period. If the need in human nutrition for such vitamin has not been established, the label shall also bear

21 U.S.C. § 352 (a)[4] in that their accompanying labeling—consisting of certain leaflets and various issues of a newsletter—falsely represented "when viewed in [their] entirety as well as through specific claims . . . that nearly everyone in this country is suffering from malnutrition or

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the statement 'The need for . . . in human nutrition has not been established,' the blank to be filled in with the name of such vitamin. . . .

§ 125.4 *Label statements relating to minerals.* (a) (1) If a food purports to be or is represented for special dietary use by man by reason of its mineral property in respect of:

Calcium,
Phosphorus,
Iron, or
Iodine,

the label . . . shall bear a statement of the proportion of the minimum daily requirement for such element supplied by such food when consumed in a specific quantity during a period of one day. . . .

(2) If a food purports to be or is represented for special dietary use by man by reason of its mineral property in respect of any element not listed in subparagraph (1) of this paragraph, the label shall bear a statement of the quantity of such element in a specified quantity of such food. Except in the case of foods subject to § 125.9, the quantity of food specified as required in this section shall be the quantity customarily or usually consumed during a period of one day, or a quantity reasonably suitable for and practicable of consumption within such period. If the need in human nutrition for such element has not been established, the label shall also bear the statement 'The need for.....in human nutrition has not been established,' the blank to be filled in with the name of such element. . . . (21 C.F.R. 247-49 (1955))

[4] § 352. Misbranded drugs and devices.

A drug or device shall be deemed to be misbranded—

(a) If its labeling is false or misleading in any particular.

in danger of such suffering because of demineralization and depletion of soils and the refining and processing of foods, that particularly all illnesses and diseases of mankind are due to improper nutrition, that said article[s] possessed nutritive properties superior to any other vitamin and mineral supplement, that said article[s] would be effective in the cure, treatment, and prevention of the ills and diseases of mankind," including certain specific diseases; and which were (b) misbranded under 21 U.S.C. § 352 (f) (1)[5] in that their labeling failed to bear adequate directions for the use for which they were intended, namely, for treatment of the specific diseases which appellants represented that the drugs could cure or prevent.

Counts III and V named two products similar to the vitamin and mineral products specified in Counts I and II, and alleged that the said articles (being also articles of "drug" within the meaning of the statutory definition) were introduced into interstate commerce on or about July 28, 1953, and July 14, 1953, respectively, consigned to the Delvita Company, Wilmington, Delaware, and to one Joseph T. Stoeckl, of Buffalo, New York, respectively, and were (a) misbranded under 21 U.S.C. § 352 (a) in that their labeling, when viewed in its entirety, falsely represented and suggested that "nearly everyone in this country is suffering from malnutrition or is in danger of such suffering because of the demineralization and depletion of soils and the refining and processing of foods, that practically all human ailments and diseases are traceable to improper nutrition, that the best way to treat, cure, and prevent all the diseases of mankind would be by using said article[s] of drug, that said article[s] [possess] nutritive properties superior to any other vitamin or mineral supplement, that

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[5] § 352. Misbranded drugs and devices.

A drug or device shall be deemed to be misbranded— . . .
(f) Unless its labeling bears (1) adequate directions for use. . . .

said article[s] constituted an adequate and effective cure, preventive and treatment" for various specific diseases; and were (b) misbranded under 21 U.S.C. § 352 (f) (1) in that their labeling failed to bear adequate directions for use.

Counts IV and VI involved a different product, known as Vit-Ra-Tox "16", whose label described it as "An Adsorbent Aid in Systematic Detoxification and An Intestinal Purificant", and alleges that said article of drug was introduced into interstate commerce on or about July 28, 1953, and December 3, 1952, respectively, and consigned to the Delvita Company, Wilmington, Delaware, and to one Joseph T. Stoeckl, of Buffalo New York, respectively, and was (a) misbranded under 21 U.S.C. § 352 (a) in that its labeling falsely represented that the article was an adequate and effective treatment for certain specific disorders and disturbances; and was (b) misbranded under 21 U.S.C. § 352 (f) (1) in that its labeling failed to bear adequate directions for use.

At the trial it was shown that appellants were engaged in the manufacture and distribution of certain "natural" vitamin products (distinguished from synthetic vitamins in that they are produced from natural food sources), and that sales of the products were made to consumers by distributors who received from appellants both the product to be sold and supporting literature. The evidence indicated that appellants recruited salespeople from among their customers and acquaintances, as well as through advertisements in newspapers. Selling techniques were explained to these people at meetings and by printed material comprising the sales kit, which contained certain leaflets in addition to supplemental newsletters written at frequent intervals by appellants and sent to such distributors. The printed promotional material was shown to be an integral part of the selling process, and constitutes the major source of the government's proof of the charges contained in the information.

The written, printed, and graphic material used was all

identified and introduced into evidence by a food and drug inspector of the Department of Health, Education, and Welfare, who had posed as a salesman in order to obtain the material from appellants. The inspector made application and became an accepted distributor; he obtained a complete sales kit, purchased products, attended a lecture by Irons, and received a series of newsletters.

At the conclusion of the trial the jury returned a verdict of guilty against both defendants on all six counts. The court sentenced V. Earl Irons to one year of imprisonment on each of the six counts, the sentences to run concurrently; and imposed upon the defendant corporation a fine of $1,000 on each count. Appeals were duly taken by both defendants.

The brief for appellants lists twelve major points as grounds for reversal, as well as a large number of subpoints. But after a complete reading of the voluminous record, we are satisfied that no error was committed by the district court.

Since appellants make no serious argument with respect to Count I, it may be dealt with summarily. The label on the carton introduced into evidence by the government states that Vit-Ra-Tox No. 21A retains "Nature's vitamins, living enzymes, synergists, and activating materials (except Vitamin D); a rich natural source of Carotene (provitamin A) and the complete natural complexes of Vitamins B, C, E, F, and K with the P fractions of the C complex and the Wulzen factor of the F complex, plus the living enzymes, synergists and mineral activators. It contains organic iron, calcium, phosphorus, iodine and a host of other minerals in trace amounts . . ." The label thus represents that the product has special dietary uses for man, by reason of its vitamin and mineral properties, within the scope of the Administrator's regulations contained in note 3, *supra;* and because there is no claim that the label satisfied the requirements of the regulations, it is quite clear that there was a violation of the Act, so far as Count I is concerned.

Before proceeding further, it is to be noted that the Act makes a distinction between the terms "label" and "labeling." Under 21 U.S.C. § 321 (k), "label" is defined to mean "a display of written, printed or graphic matter upon the immediate container of any article . . ." But by 21 U.S.C. § 321 (m), "labeling" means "all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article." It is clear that the term "labeling" must be given a broad meaning to include all literature used in the sale of food and drugs, whether or not it is shipped into interstate commerce along with the article. "One article or thing is accompanied by another when it supplements or explains it, in the manner that a committee report of the Congress accompanies a bill. No physical attachment one to the other is necessary. It is the textual relationship that is significant. *Kordel* v. *United States*, 335 U.S. 345, 350 (1948). There is no doubt that the printed circulars, pamphlets, brochures and newsletters distributed by appellants in the present case constituted "labeling" within the statutory definition, and thus may properly be received in evidence as proof of false or misleading statements.

In determining whether such labeling contained "false or misleading" statements, we must be careful not to read the literature with the eyes either of experts in nutrition or of overly skeptical buyers. What is pertinent is the effect the claims would have on those to whom they are addressed, namely, prospective purchasers and actual customers of appellants, who cannot be presumed to have special expertness or to be unduly cautious, but who are more likely than not to be persons who are pathetically eager to find some simple cure-all for the disease with which they are afflicted or who are susceptible to luridly painted scare literature as to the prospect of being disease-ridden unless they consistently partake of the vaunted drug product. This approach has been authoritatively approved.

In *Federal Trade Commission* v. *Standard Education Society*, 302 U.S. 112, 116 (1937), it is stated: "The fact that a false statement may be obviously false to those who are trained and experienced does not change its character, nor take away its power to deceive others less experienced. There is no duty resting upon a citizen to suspect the honesty of those with whom he transacts business. Laws are made to protect the trusting as well as the suspicious. The best element of business has long since decided that honesty should govern competitive enterprises, and that the rule of *caveat emptor* should not be relied upon to reward fraud and deception." See also *Donaldson* v. *Read Magazine, Inc.*, 333 U.S. 178, 188 (1948).

When appellants' labeling is examined in this light and in its entirety, it readily appears that the government introduced at least sufficient evidence to warrant submission to the jury of the issues whether appellants made the representations charged against them, and whether these representations were false or misleading.

The literature contains considerable material that is either obviously harmless or irrelevant to this case, such as lists of food with their vitamin content, instructions to salesmen, and shipping details for the various products. But, beyond that, many representations are made that, fairly interpreted, provide adequate support for the government's charges. There are, first of all, numerous assertions that "all human ailments" can be traced to nutritive deficiencies and that various specific ills are caused thereby. For example, there is the statement:

> "The evidence is overwhelming! That we Are what we Eat. That practically All Human ailments are traceable to our food. From the time we are conceived until we reach 150 lbs.;
>
> "It's The Material Out of Which we are built that determines the structure. If that material is faulty the structure Breaks Down. If it is Not faulty, it does Not Break Down . . . It's our Food, that makes us sick or well."

Similarly, in one of appellants' pamphlets it is stated: "We believe that practically all the ailments that beset our civilized world are caused by deficient foods which can lower one's resistance."

With respect to specific diseases, the literature quotes from the writings of one Dr. Sutherland* that:

> "At the present time many conditions are considered as essentially deficiency diseases and are associated in one's thought with the classical Beri-Beri, Pellagra, Rickets and Scurvy. Such conditions are Infantile Scorbutus, Marasmus, Dentition Difficulties and Imperfect Teeth in Children and Adults, Dyspepsias, Indigestions, Diarrhoeas and Constipation, Obesity, Inability to Nurse Children, Diabetes, Neuroses, Infantile Paralysis, Certain Myalgias or 'Rheumatism,' Dementia Praecox, and even Tuberculosis and Cancer. The list can be extended but it is already a formidable one."

Furthermore, there are numerous examples in the record of statements attributing extraordinary powers to appellants' products:

> "Our customers are indeed fortunate that Vit-Ra-Tox was chosen by Green Life Products Co. of Kansas City, as the First and Only organization of its Kind to offer to the public Green Life, the richest, most potent and easily assimilated Natural Food known to man.
>
> We believe that Green Life, because of its high concentration of Nature's unknown mysteries, is at present the only hope for overcoming the deficiencies of civilized, processed foods. Green Life alone should be able to help lessen current deficiencies in an average reasonable daily diet if the right amount for each individual can be determined through experience."

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* The literature employs quotations from the writings of others. It is obvious that so long as these writings are quoted with approval, they become the representations of appellants and can be used by the government to sustain its charges.

At another point appellants modestly state in an unqualified way that "It [Vit-Ra-Tox No. 21] is the One Hope for suffering humanity." And again, that " 'This Product' *alone* of all products now on the market has *all* the vitamins, minerals, enzymes, co-enzymes, mineral activators and synergists (co-workers or helpers) needed by the human body (except Vitamin D)."

Apart from these general representations about the value of their product, the record discloses that appellants claimed the power to cure or ameliorate specific diseases. These claims are to be found both with respect to the products which were the subject of Counts II, III and V, and also with respect to those which were the subject of Counts IV and VI. Regarding the products mentioned in Counts II, III and V, it is said: "Hence Dr. Lee believes that arthritis cannot possibly reside permanently in a *body* which has a sufficient daily intake of this product." And, again quoting Dr. Lee,[1] "No one could continue to have arthritis and use this product daily."

With respect to Vita-Ra-Tox 16 (the Bentonite product) referred to in Counts IV and VI, a book of appellants' which was provided to all distributors quoted, somewhat out of context, from U.S. Government Bureau of Mines Booklet No. 609: "Moistened with water or glycerin, it ["Alkali Bentonites"] also has been used, apparently with some

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[1] The newsletter containing the second statement attributed to Dr. Lee said: "The above is what Dr. Lee thinks of the base of our new product and we consider him tops, the best authority on vitamins and minerals in the country today." Dr. Lee testified at the trial. It appeared that he was a licensed dentist (1924) not presently practising dentistry but whose "principal business" was the Lee Engineering Company which manufactured custom-made electrical equipment.

There was evidence that these representations were effective to induce purchases of "Green Life". One witness testified that he was told, when handed the literature, that the product would cure arthritis and that he bought it for that purpose.

success, for rheumatic and pulmonary affections, disorders of the scrofulous and eczeatous type, abscesses, and the cleansing of sores and wounds."

Laying aside these specific claims, it is true that most of the representations in the literature relating to diseases are more indirect; virtues of appellants' products are juxtaposed with descriptions of the symptoms or cures for various diseases, although no statement is made overtly correlating the products with the diseases. For example, the first few pages of one of the pamphlets are devoted to very general statements about nutritive deficiencies in the United States; it then goes on to say:

> "No one can listen to the radio or television day after day without being reminded of the enormity of this health problem. Constantly we hear appeals for donations to the Heart Fund on the grounds that over 50% of all the deaths in 1951 were due to Heart trouble of some kind. Yet in 1890 only 5% of the deaths were from Heart Disease. This indicates a 1,000% increase in 60 years. Can anyone doubt that this is a major problem?
>
> In their recent plea, the Cancer Fund announced that one-fifth of those now living will die of Cancer (1/5th of 150,000,000 is 30,000,000). Since 1890 the percent of Deaths from Cancer has increased 650%. In the drive for a better understanding of Diabetes it was broadcast and advertised that 1,000,000 people in the country have Diabetes that don't know they have it. Dr. Joslin, the greatest living authority on Diabetes states that at the rate we are going, almost everyone in America will have Diabetes within 50 years."

Later on in the same pamphlet appellants proceed to discuss the virtues of their products: "To the best of our knowledge there is absolutely nothing on the market today with which Vit-Ra-Tox #16 can be compared. It seems to have the faculty of assisting the body in removing toxins and poisons." Another example of the juxtaposition of a discussion of appellants' products with a

discussion of specific diseases is contained in one of the newsletters in which, under the heading "The Garlic Cure for Tuberculosis", there is a long exposition of certain alleged cures of tuberculosis by garlic and garlic products. The latter part of the newsletter contains information for salesmen as to how to speed up their orders for the Vit-Ra-Tox products which contain a garlic derivative. The record discloses many other illustrations of references to specific diseases cleverly coupled with boosts for or information concerning Vit-Ra-Tox. On the basis of this record it is not at all surprising that a lay jury reading the literature came to the conclusion that special curative or at least preventive powers for the diseases mentioned were claimed by appellants for their Vit-Ra-Tox line.[8] And if such was the impression made upon the jury, it seems more than likely that a prospective pur-

[8] On its cartons and in one or two of appellants' newsletters or pamphlets, one may find disclaimers such as the following:

> "Important—We do not diagnose or prescribe
>
> "Neither we nor our Vit-Ra-Tox Distributors are doctors. We do not attempt to diagnose or prescribe. We do not approach our customer's health problem from the standpoint of specific ailments. We are however, interested in teaching them how, to the extent possible through nutritional influences, we can help them. . . .
>
> "Our sales talk and theory of body building through nutritional elements are not to be interpreted as entering the field of medicine or as violating a doctor's prerogative. Since, therefore, we try only to improve the nutritional vitality of our customers, if any dangerous acute conditions exist or are suspected, a physician should be consulted."

Such disclaimers occur only rarely. And even when they appear in conjunction with some of the literature found to be false or misleading, they should not be regarded as conferring any immunity on appellants so long as the literature in its entirety is reasonably understood by readers to make the curative claims alleged by the government.

chaser, hoping finally to obtain relief from a long-endured disease, would not read appellants' literature with any skeptical literalness. Bearing in mind the broadly remedial purposes of the Act in preventing deception, the Congress must be taken to have meant to strike not only at palpably false claims but also at clever indirection and ambi-guilty in the creation of misleading impressions. See *United States* v. *One Device, Intended for Use as a Colonic Irrigator*, 160 F. 2d 194, 200 (C.A. 10th, 1947).

In order to show that many of the representations contained in the literature, or labeling, were "false or misleading," the government put on the stand five expert medical witnesses, authorities in the field of nutrition or internal medicine.

These experts testified, first of all, that not all human illnesses are traceable to nutritive deficiencies, as appellants claimed, pointing out that some diseases are caused by congenital defects, others by specific viruses or bacteria, and that numerous degenerative diseases of old age have nothing to do with nutrition. Moreover, they stated that, after experiments with appellants' products, these were found to lack the powers attributed to them, either as general aids to health or in connection with the specific diseases mentioned in the literature. One doctor said: "In the directions recommended, it would have absolutely no effect in any of the ten leading causes of death in the United States, or in any other way you would like to take it." There is no need to recite the evidence in detail, for the record is replete with medical testimony contradicting the various claims; and there is no doubt that the jury was provided with a sufficient foundation for its findings.

Appellants introduced their own expert witnesses at the trial, but it does not take one well versed in the field of nutrition to appreciate why the jury might have accorded their testimony diminished weight. One of them was a soils expert who was not shown to be qualified to discuss human nutrition or the claim that soil deficiency re-

sulted either in national malnutrition or in diseases of man. Several practising physicians also testified, but none seemed to possess extensive qualifications in nutrition. One of these, who had not practised medicine for over thirty years, testified to laboratory tests he made for high blood pressure using garlic on cats and on humans, but he admitted on cross-examination that, to supply a daily dose comparable to the dose of garlic administered in his tests, he would have to give a patient 855 tablets of Vit-Ra-Tox 21B per day. Appellants also presented two dentists, neither of whom disclosed any additional training to equip them as an expert in nutrition, and one of whose writings—those of Dr. Lee—had been employed as part of appellants' sales literature. See note 7, *supra*. Incidentally, this is the Dr. Lee whom one of the government's experts caustically referred to as "known as one of the biggest charlatans in the food quackery business." The jury, after hearing these expert witnesses for both sides, was in a position to compare their respective qualifications, and we are not prepared to set aside its determination as to where the truth lay.

Concerning the accuracy of therapeutic claims, it was held in an earlier mail fraud case that fraud could not be found to exist so long as bona fide differences of medical opinion existed, *American School of Magnetic Healing* v. *McAnnulty*, 187 U.S. 94 (1902). But the terms of the Federal Food, Drug, and Cosmetic Act of 1938, outlawing "false or misleading" labeling, and the regulations issued under the Act, proceed upon a different basis. One may be guilty of the misdemeanor described in 21 U.S.C. § 333 (a) without having any intent to defraud or mislead. In contrast with this is the provision of § 333(b), which imposes more severe penalties in case of a violation of any of the provisions of § 331, "with intent to defraud or mislead." In the applicable regulations it is provided: "The existence of a difference of opinion, among experts qualified by scientific training and experience, as to the

truth of a representation made or suggested in the labeling is a fact (among other facts) the failure to reveal which may render the labeling misleading, if there is a material weight of opinion contrary to such representation." 21 C.F.R. § 1.3. The cases decided under the Act indicate that the jury will be allowed to determine the truth of a therapeutic claim as it would that of any other fact. *United States* v. *Kaadt*, 171 F. 2d 600, 603 (C.A. 7th, 1949). The danger has been pointed out, in 67 Harv. L. Rev. 632 at 654, "that juries, if always allowed to determine the validity of a claim after hearing contradictory medical testimony, will brand false new, temporarily unpopular, but possibly correct scientific theories." On the other hand, the potentiality of harm to gullible consumers, from acceptance of false or misleading representations, may be just as real even though the maker of the representations has a bona fide belief in their truth. Which of these more or less competing considerations is to be accorded priority is, of course, a matter of policy for the Congress to decide. See *United States* v. *Dotterweich*, 320 U.S. 277, 284-85 (1943).

It must be remembered that a representation may be "misleading" from the very fact of overemphasis and exaggeration, even though the product in question may be helpful, and in some circumstances, useful, though not really indispensable to good health. This is no doubt what one of the government's expert witnesses had in mind when he testified:

> "Well, obviously food is important, and we have to develop our bodies from building materials and blocks we get from food; but in order to utilize our food properly we have to have a liver that is functioning, and a pancreas that is functioning, and various other of our body organs, in order to utilize food properly. So we may very well get the best of food, and yet if we have faulty processes of digestion, or liver functioning, which is mentioned specifically, we can't get the most out of our food. On the other hand,

if we have a good liver and a good pancreas and a good insides, you might say, working properly and we get poor food, we aren't going to do a good job either, so the answer to the last part is Yest or No, food is important but other things are also important."

The same expert testified subsequently, on cross-examination:

"If anybody eats nothing but sugar, that is, this white sugar you mentioned nothing but white bread, you would need some type of vitamin and mineral supplement. If you put in a little milk, if you put in a little meat, if you put in a little egg, vegetable, fruits, you don't need Mr. Irons or anybody else, if you are in good health."

Turning now to the second charge contained in each of Counts II-VI of the information, that is, that the articles of drug were misbranded in that their labeling failed to bear "adequate directions for use" for the various diseases and conditions for which they were intended, it may be pointed out that we are free to look to all relevant sources in order to ascertain what is the "intended use" of a drug, and are not merely confined to the labels on the drug or the "labeling". The legislative history of the 1938 Act makes this clear. See Dunn, Federal Food, Drug, and Cosmetic Act 111-12, 240 (1938). Such also has been the undeviating opinion of the courts which have had occasion to deal with the issue. For example, in a recent decision the Third Circuit said:

"The intended uses of the products in the present issue as in *Kordel* [*Kordel* v. *United States*, supra, 335 U. S. 345] were to cure, ameliorate or prevent diseases. The evidence to prove their uses included both graphic materials distributed and testimony of oral representations to users and prospective users. The latter are no less relevant on the question than the former. Both show that the products shipped were to be used as drugs." *United States* v. *El Rancho Adolphus Products et al.*, F. 2d (C.A. 3d Jan. 29,

1957). See also *United States* v. *3 Cartons, More or Less, No. 26 Formula GM etc.,*" 132 F. Supp. 569, 574 (S.D. Cal. 1952).

In the present case, therefore, we are entitled to utilize all of appellants' literature as well as the oral representations made by V. Earl Irons at his lectures or by authorized sales distributors.*

As a matter of fact, appellants introduced no label which provided adequate directions if the use of the products is to be taken to effect the cure or prevention of the various diseases mentioned in the literature. Indeed, appellants do not maintain that they ever issued any such label, but content themselves in saying that the government's case must fall because there was no showing that the voluminous literature admitted in evidence constituted *all* of the labeling of the products; in other words, it is argued that other items of labeling which might exist might have contained adequate directions for use. But once the government has introduced into evidence a substantial number of documents constituting "labeling" of the various drug products, none of which provided "adequate directions for use", it seems perfectly reasonable to require that the defendants have the burden of going forward with the production of other labeling which does satisfy the demands of the statute. It would be quite unthinkable to impose upon the government the further necessity of proving that there are no other, secreted, labelings in existence, especially since all such literature used by appellants can be assumed to be in their possession. Therefore we find no error in the conclusion that the labeling of appellants' products did not provide adequate directions for use.

Appellants present a variety of other defenses, some of which are clearly untenable. For example, it is a bit late in

* The following testimony of the food and drug inspector about a speech made by appellant V. Earl Irons was thus admissible in order to show the intended use of the products.

the day to sustain the assertion that the Federal Food, Drug and Cosmetic Act is unconstitutionally vague. Nor, after a review of the entire record, are we able to agree that the court below committed prejudicial procedural errors in its conduct of the trial.

However, the propriety of the sentences imposed merits a brief comment. It is argued that Counts I and II of the information and Counts III and IV each charged but a single offense and therefore that it was an error to sentence appellants separately on each of these four counts. (The individual defendant is hardly in a position to raise this point, since the sentences imposed upon him were to run concurrently. However, separate fines were imposed upon the corporate defendant as to each count.) The rule is now well settled that a conviction with sentence upon one indictment or information does not bar conviction with sentence upon another "if the evidence required to support the one would not have been sufficient to warrant the conviction upon the other without proof of an additional fact. . . ." *Eberling* v. *Morgan*, 237 U.S. 625, 631 (1915); *Ekberg* v. *United States*, 167 F. 2d 380, 384 (C.A. 1st, 1948). In the present case this test is satisfactorily met. The violation in Count I is based upon the charge that the article was represented as a food for special dietary uses by reason of its vitamin and mineral content, and that the label did not bear certain information required under the authorized regulations issued by the Secretary of Health, Education, and Welfare. In contrast, Count II alleges the same product to be a misbranded drug on the basis of false and misleading statements which appear on the "labeling" literature disseminated by appellants; and to obtain a conviction under this count the government had to prove the additional fact that the statements contained in such literaure were false or misleading.

The arguments based on Counts III and IV are even more flimsy, for these counts involve entirely different drugs. The drug named in Count III is a tablet known as Vit-Ra-

Tox No. 21, which is said on its label to contain "a mixture of dried extracted juices of cereal grasses green life, plus bone meal, brewer's yeast, fish liver oils, alfalfa kelp (or dulse)." The drug which is the subject of Count IV is a liquid known as Vit-Ra-Tox No. 16, described in the label thus: "Colloidal Bentonite (U.S.P. Grade). Distilled water as vehicle with certified flavor and color". Obviously they are different drugs. As the statute forbids the introduction into interstate commerce of *any* drug that is adulterated or misbranded (21 U.S.C. § 331 (a)), Counts III and IV do not charge the commission of a single offense but rather two separate and distinct offenses, and the sentence imposed upon the corporate defendant by the trial court was therefore entirely proper.

A judgment will be entered affirming the judgments of the District Court.

Judgment

DISTRICT COURT

No. 54-374-F Criminal

UNITED STATES OF AMERICA

v.

V. EARL IRONS

On this 22nd day of October, 1956 came the attorney for the government and the defendant appeared in person and by counsel.

IT IS ADJUDGED that the defendant has been convicted upon his plea of not guilty and a Verdict of guilty of the offense of Violation of the Federal Food, Drug and Cosmetic Act, (Title 21 U.S.C. 331 and 333) Misbranded article of drug—6 counts as charged in said information and the court having asked the defendant whether he has anything

to say why judgment should not be pronounced, and no sufficient cause to the contrary being shown or appearing to the Court,

IT IS ADJUDGED that the defendant is guilty as charged and convicted.

IT IS ADJUDGED that the defendant is hereby committed to the custody of the Attorney General or his authorized representative for imprisonment for a period of ONE YEAR on each count of the information said prison sentences to run concurrently and to commence on Monday, November 5, 1956.

IT IS ORDERED that the Clerk deliver a certified copy of this judgment and commitment to the United States Marshal or other qualified officer and that the copy serve as the commitment of the defendant.

(s) FRANCIS J. W. FORD,
United States District Judge

Judgment

DISTRICT COURT

No. 54-374-F Criminal

UNITED STATES OF AMERICA

v.

V. E. IRONS, INC., *a corporation*

On this 22nd day of October, 1956 came the attorney for the government and the defendant corporation appeared by its duly appointed counsel.

IT IS ADJUDGED that the defendant has been convicted upon his plea of not guilty and a verdict of guilty of the offense of Violation of the Federal Food, Drug and Cosmetic

Act, (Title 21 U.S.C. 331 and 333) Misbranded article of drug—6 counts as charged in said information and the court having asked the defendant whether he has anything to say why judgment should not be pronounced, and no sufficient cause to the contrary being shown or appearing to the Court,

IT IS ADJUDGED that the defendant Corporation pay a fine of $1,000.00 on each count of the information, a total of $6,000.00 on entire information.

IT IS ORDERED that the Clerk deliver a certified copy of this judgment and commitment to the United States Marshal or other qualified officer and that the copy serve as the commitment of the defendant.

(s) FRANCIS J. W. FORD,
United States District Judge

Judgment

COURT OF APPEALS

April 24, 1957.

This cause came on to be heard on consolidated appeals from the United States District Court for the District of Massachusetts, and was argued by counsel.

Upon consideration whereof, It is now here ordered, adjudged and decreed as follows: The judgments of the District Court are affirmed.

By the Court:

/s/ ROGER A. STINCHFIELD,
Clerk.

Thereafter, on May 8, 1957, mandate was stayed until further order of the Court.

APPENDIX B

Statutes

The Federal Food, Drug, and Cosmetic Act of June 25, 1938, c. 675, 52 Stat. 1040 (21 U.S.C. 301, et seq.), provides in pertinent part:

Sec. 201 (m). The term "labeling" means all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article (21 U.S.C. 321 (m)).
Sec. 301. The following acts and the causing thereof are hereby prohibited:

(a) The introduction or delivery for introduction into interstate commerce of any food, drug, device, or cosemetic that is adulterated or misbranded. (21 U.S.C. 331 (a)).

Sec. 502. A drug or device shall be deemed to be misbranded—

(a) If its labeling is false or misleading in any particular (21 U.S.C. 352 (a)).

(f) Unless its labeling bears (1) adequate directions for use; and (2) such adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users: *Provided,* That where any requirement of clause (1) of this paragraph, as applied to any drug or device, is not necessary for the protection of the public health, the Secretary shall promulgate regulations exempting such drug or device from such requirement. (21 U.S.C. 352 (f)).

18 U.S.C. 2. Principals.

(a) Whoever commits an offense against the United States or aids, abets, counsels, commands, induces or procures its commission, is punishable as a principal.

(b) Whoever wilfully causes an act to be done which if directly performed by him or another would be an offense against the United States, is punishable as a principal. (As amended Oct. 31, 1951, C. 655, § 17b, 65 Stat. 717).

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In the Supreme Court of the United States

OCTOBER TERM, 1956

No. 1026

V. E. IRONS, INC., AND V. E. IRONS, PETITIONERS

v.

UNITED STATES OF AMERICA

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FIRST CIRCUIT

BRIEF FOR THE UNITED STATES IN OPPOSITION

OPINION BELOW

The opinion of the Court of Appeals (Pet. App. 1a–20a) is not yet reported.

JURISDICTION

The judgment of the Court of Appeals was entered on April 24, 1957 (Pet. App. 22a). The petition for a writ of certiorari was filed on May 23, 1957. The jurisdiction of this Court is invoked under 28 U. S. C. 1254 (1).

QUESTIONS PRESENTED

1. Whether Section 502 (f) (1) of the Federal Food, Drug, and Cosmetic Act is rendered vague and indefinite because oral recommendations and advertising

(not labeling) as to the curative effect of drugs were considered in determining whether products sold as drugs bore adequate statements of intended use.

2. Whether wilfullness must be established under 18 U. S. C. 2 (b) by virtue of the fact that the information charged petitioners with "causing" the introduction of misbranded products into interstate commerce.

3. Whether it was reversible error for the trial judge to preclude one of petitioners' expert witnesses from giving his personal opinion as to whether the literature claimed that the drugs would cure specific diseases.

STATUTES AND REGULATION INVOLVED

Section 201 of the Federal Food, Drug, and Cosmetic Act, 52 Stat. 1040, 21 U. S. C. 321, provides in pertinent part:

> For the purposes of this Act—
>
> * * * * *
>
> (g) The term "drug" means * * * (2) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; * * *
>
> * * * * *
>
> (k) The term "label" means a display of written, printed, or graphic matter upon the immediate container of any article; * * *
>
> * * * * *
>
> (m) The term "labeling" means all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article.
>
> * * * * *

Section 301, 52 Stat. 1042, 21 U. S. C. 331, provides in pertinent part:

> The following acts and the causing thereof are hereby prohibited:
>
> (a) The introduction or delivery for introduction into interstate commerce of any * * * drug * * * that is * * * misbranded.
>
> * * * * * *

Section 502, 52 Stat. 1050, 21 U. S. C. 352, provides in pertinent part:

> A drug * * * shall be deemed to be misbranded—
>
> (a) If its labeling is false or misleading in any particular.
>
> * * * * * *
>
> (f) Unless its labeling bears (1) adequate directions for use; * * *.
>
> * * * * * *

21 C. F. R. § 1.106 provides in pertinent part:

> *Drugs and devices; directions for use—*
>
> (a) *Adequate directions for use.* "Adequate directions for use" means directions under which the layman can use a drug or device safely and for the purposes for which it is intended. Directions for use may be inadequate because (among other reasons) by omission, in whole or in part, or incorrect specification of:
>
> (1) Statements of all conditions, purposes, or uses for which such drug or device is intended, including conditions, purposes, or uses for which it is prescribed, recommended, or suggested in its oral, written, printed, or graphic advertising, and conditions, purposes, or uses for which the drug or device is commonly used; * * *.
>
> * * * * * *

18 U. S. C. 2 provides in pertinent part:

§2. Principals.

* * * * *

(b) Whoever willfully causes an act to be done which if directly performed by him or another would be an offense against the United States, is punishable as a principal.

STATEMENT

Following a jury trial held in the United States District Court for the District of Massachusetts, petitioners were convicted under a six-count information charging that they had caused misbranded products to be introduced into interstate commerce in violation of the Federal Food, Drug, and Cosmetic Act, 52 Stat. 1040, as amended, 21 U. S. C. 301, *et seq.* Count I charged the introduction into interstate commerce on or about December 16, 1952, of Vit-Ra-Tox No. 21 A and B ("A NATURAL FOOD *with green* life") in violation of Section 403 (j) of the Act, and the regulations promulgated thereunder, in that, although this product was represented on the container as a food for special dietary uses because of its vitamin and mineral content, its label failed to contain required information concerning its vitamin and mineral properties (R. 5–8). Counts II–VI charged that petitioners caused the introduction of misbranded drugs (varieties of Vit-Ra-Tox) into interstate commerce on various occasions in 1952 and 1953, in that the labeling of said drugs was false and misleading in violation of Section 502 (a) of the Act (*supra,* p. 3) and failed to bear adequate direc-

tions for use in violation of Section 502 (f) (1) of the Act (*supra*, p. 3) (R. 8–21).

On October 22, 1956, petitioner V. E. Irons was sentenced to imprisonment for one year on each of the six counts to run concurrently (R. 733). The corporate petitioner was fined $1,000 on each count of the information (R. 734). In an opinion by Chief Judge Magruder, the Court of Appeals for the First Circuit unanimously affirmed the convictions (Pet. App. 1a–20a).

The evidence adduced at the trial may be summarized as follows:

Petitioners distributed various varieties of Vit-Ra-Tox and literature relating to these products (Gov. Ex. 26; R. 149, 783–822, 802–810) to distributors and salesmen in various sections of the country who then retailed these products to customers directly in their homes or offices. These distributors were recruited from customers, acquaintances, and through newspaper advertisements (R. 33–42, 76–80, 134–143, 147–156, 386–387; Gov. Ex. 26; R. 149, 783–821, 814–820).

Petitioner Irons, the president and treasurer of the corporate petitioner (R. 26–27), decided on the physical composition of Vit-Ra-Tox and prepared all the literature relating to the product (R. 382–385). This literature consisted of pamphlets, newsletters, package inserts, letters to customers, and leaflets (R. 735–981, 1007–1008, 1027).

The theme underlying this mass of material was that all human ailments and diseases may be traced to nutritive deficiencies; that nearly everyone is suffering from malnutrition; and that Vit-Ra-Tox would

ameliorate and cure these various diseases (*e. g.*, Gov. Ex. 27; R. 148–149, 833–902, 851). In a pamphlet entitled WHAT PRICE REFINEMENT, sold to salesmen to be left with prospective customers (Gov. Ex. 4; R. 40, 58, 735–740, 737), a Dr. Sutherland is quoted approvingly for the statement that:

> At the present time many conditions are considered as essentially deficiency diseases and are associated in one's thought with the classical Beri-Beri, Pellagra, Rickets and Scurvy. Such conditions are Infantile Scorbutus, Morasmus, Dentition Difficulties and Imperfect Teeth in Children and Adults, Dyspepsias, Indigestions, Diarrhoeas and Constipation, Obesity, Inability to Nurse Children, Diabetes, Neuroses, Infantile Paralysis, Certain Myalgias or "Rheumatism," Dementia Praecox, and even Tuberculosis and Cancer.

Certain of the literature specifically extolled the curative effect of Vit-Ra-Tox or of the ingredients contained therein. Thus, Vit-Ra-Tox No. 21, containing a mixture of dried extracted juices of cereal grasses, was claimed as a cure for arthritis (Gov. Exs. 14 and 15; R. 73, 763–770). Garlic, an ingredient of Vit-Ra-Tox No. 21 B, was said in the literature to be comparable to penicillin and had been customarily used for diphtheria, respiratory infections, boils, carbuncles, and suppurating sores (R. 268–269; Gov. Ex. 9; R. 58, 749–752). Bentonite, contained in Vit-Ra-Tox No. 16, was indirectly recommended for cleansing the brain, nervous system, blood, muscles, and tissues of the body (R. 319; Gov. Ex. 26; R. 149, 783–822, 802–806).

To establish that these and other claims contained in the literature distributed by petitioners were false, the Government called several experts (including Dr. Frederick J. Stare, Professor of Nutrition and Head of the Department at Harvard Medical School, and Dr. Leonard A. Maynard, Professor of Nutrition, Emeritus, Cornell University, formerly Director of its School for Nutrition), who testified that Vit-Ra-Tox or its ingredients would not cure the various diseases referred to in the literature (R. 105–131, 198–209, 234–244, 260–274, 296–307, 315–328). Several witnesses, including two dentists and three physicians, testified as experts for petitioners (R. 397–458, 519–544, 586–595, 607–636, 658–669).

As to the charge of misbranding, under Counts II–VI, in that the labeling of the drugs failed to contain adequate directions for use, the jury was instructed to consider all claims, whether contained in the literature or in oral representations of petitioner Irons and one of the salesmen, if they found that "* * * any [such] claims are made for the cure, prevention or mitigation of disease" (R. 699, 703–704). On the charge of false labeling contained in the same counts, the jury was charged to consider only that portion of the literature it deemed to be "labeling" (R. 699), defined by the trial judge as that literature employed in the sale or use of the product or to promote such sale or use (R. 699).

The oral recommendations made by petitioner Irons occurred during a "talk to distributors" (R. 158) attended by a Food and Drug Inspector in the guise of

a salesman (R. 157). The inspector testified that Irons discussed cancer, female troubles, sexual impotence, and sexual perversion (R. 159). He mentioned a woman whose menstrual difficulties ceased with the taking of Vit-Ra-Tox (R. 159). He noted that "* * * cancer can be cured in three to ten weeks"; that such cure was then being successfully accomplished with potassium salts; and that potassium salt was specified as an ingredient on the label of Vit-Ra-Tox (R. 160). The other oral representation was made by a salesman of Vit-Ra-Tox. One Elmer Struckmeyer testified that he purchased Vit-Ra-Tox No. 21 because he was told it would cure arthritis—a disease from which he suffered (R. 386–389).

ARGUMENT

1. With respect to the construction of the statute, no issue is raised as to Count I of the information. Nor do petitioners challenge that part of Counts II–VI which charges false and misleading labeling—a charge squarely within *Kordel* v. *United States,* 335 U. S. 345. Their attack, in this aspect of the case, is only on that portion of Counts II–VI which charged a violation of Section 502 (f) (1) of the Act (*supra,* p. 3) requiring labeling of drugs to contain directions for use. They argue that, if the section applies to products recommended as treatment for diseases in oral statements and advertising other than labeling, the section is unconstitutionally vague and indefinite (Pet. 5–9).[1]

[1] Oral statements were actually only a minor part of the proof in this case.

A similar argument was recently rejected by the Third Circuit in *United States* v. *Adolphus Hohensee, et al.*, Nos. 11,977–11,979, decided on January 29, 1957. This court denied certiorari on May 27, 1957, No. 909, this Term. Further review is equally unwarranted in the instant case.

Under administrative regulation (*supra*, p. 3) and undeviating court decision, all relevant representations—whether labeling or not—may properly be considered to determine the purposes, diseases, and conditions for which a drug is intended. *E. g., Alberty Food Products* v. *United States*, 185 F. 2d 321, 325–326, and 194 F. 2d 463, 464 (C. A. 9); *Colgrove* v. *United States*, 176 F. 2d 614, 615 (C. A. 9), certiorari denied, 338 U. S. 911; *United States* v. *El-O-Pathic Pharmacy*, 192 F. 2d 62, 77 (C. A. 9); *United States* v. *Cruez*, 144 F. Supp. 229 (E. D. Ill.); *United States* v. *3 Cartons, etc.*, 132 F. Supp. 569 (S. D. Cal.); *United States* v. *Vitamin Industries Inc.*, 130 F. Supp. 755, 765 (D. Neb.).

If the rule were otherwise, it would be a simple matter to circumvent Section 502 (f) (1) merely by limiting curative claims to oral representations. There is certainly nothing uncertain in requiring a person to specify directions for use for the various diseases he represents a drug will cure, regardless of the media of expression he chooses for making such representations. "The high purpose of the Act [is] * * * to protect consumers who under present conditions are largely unable to protect themselves in this field. * * *." *Kordel* v. *United States*, 335 U. S. 345, 349; *United States* v. *Sullivan*, 332 U. S. 689; *United*

States v. *Dotterweich*, 320 U. S. 277. Loopholes should not be created by "strained and technical constructions * * *." *Kordel, supra*, at p. 349; *United States* v. *Urbuteit*, 335 U. S. 355, 357–358.

Nor is there any merit to petitioners' further allegation that the oral representations, not being labeling, were not relevant in a prosecution under the Federal Food, Drug, and Cosmetic Act, but that prosecution for their content was solely within the exclusive jurisdiction of the Federal Trade Commission (Pet. 8–9). The truth or falsity of the oral representations and the literature, when considered on the charge of inadequate directions for use, was not in issue. Their consideration was properly limited to whether the labeling bore adequate directions for use for the diseases for which the products were intended. See *Alberty Food Products* v. *United States*, 194 F. 2d 463, 464 (C. A. 9); cf. *Kordel* v. *United States*, 335 U. S. 345, 351.

2. Petitioners contend (Pet. 9–11) that, since each of the six counts charged petitioners with "causing" the entry into interstate commerce of a misbranded product, wilfullness was made an essential element of the offense pursuant to 18 U. S. C. 2 (b), which provides that one who "wilfully" causes an act to be done is liable as a principal. Even on petitioners' theory, the requisite "wilfullness" would relate only to the introduction into interstate commerce, since it is well established that intent is not an essential element of the offense of misbranding under the Federal Food, Drug, and Cosmetic Act. *United States* v. *Dotterweich*, 320 U. S. 277, 285–286; *United States*

v. *Kaadt*, 171 F. 2d 600, 604 (C. A. 7). Since there was no real issue as to the fact that petitioners did intentionally ship their products in interstate commerce, the contention has no substance in relation to the facts of this case.

In any event, petitioners misread 18 U. S. C. 2 (b). It is quite plainly a general statute which, insofar as material, was designed to impose liability for causation where other statutes do not do so. It has no application here, since Section 301 of the Federal Food, Drug, and Cosmetic Act by its own terms specifically prohibits "causing" the introduction of misbranded products in interstate commerce.

3. Almost at the end of the direct examination of a Dr. Philip Norman, one of the physicians called by petitioners as an expert witness, the trial judge, upon the Government's objection, precluded him from answering questions as to whether, from a reading of petitioners' literature, he had "* * * an opinion as to whether or not the defendants are claiming cures for specific diseases" (R. 455–456). During Dr. Norman's lengthy direct testimony prior to said question, he had, among other things, given his opinion that the theories of nutrition set out in petitioners' literature were true, and had attributed indigestion, anemia, nervousness, varicose veins, hay fever, asthma, tuberculosis, and cancer to improper nutrition (R. 397–455, 422–427). The court agreed with the Government that the witness was not qualified, but excluded the question primarily on the ground that "it is a factual question for the jury" (R. 456).

The ruling was clearly correct. "The Federal Food, Drug, and Cosmetic Act was not made for experts * * * [but] is to protect the public, the vast multitude which includes the ignorant, the unthinking, and the credulous who, when making a purchase, do not stop to analyze." *United States* v. *62 Packages, etc.*, 48 F. Supp. 878, 887 (W. D. Wis.), affirmed, 142 F. 2d 107 (C. A. 7), certiorari denied, 323 U. S. 731; *Kordel* v. *United States*, 335 U. S. 345, 349; *United States* v. *Urbuteit*, 335 U. S. 355, 357–358; cf. *Federal Trade Commission* v. *Standard Education Society*, 302 U. S. 112, 116. It was for the jury to say whether petitioners were representing to the public that their product would cure disease.

Petitioners' reliance on *United States* v. *38 Dozen Bottles, Etc.*, 114 F. Supp. 461 (D. Minn.), is misplaced. In that case, one of the Government's experts, a specialist in internal medicine, did not disclose his own opinion of the advertisement, but his opinion of the impression that ulcer patients might receive (114 F. Supp. at 463). The other Government experts in that case were noted advertising and marketing specialists who had exhaustingly analyzed the advertisement and interviewed 200 persons concerning their impressions of the advertisement (114 F. Supp. at 462–463). In the instant case, petitioners' witness was a practicing physician (R. 398), who was asked merely to give his personal opinion of what the representations would mean to him.

CONCLUSION

For the foregoing reasons, it is respectfully submitted that the petition for a writ of certiorari should be denied.

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